

105TH CONGRESS
2D SESSION

H. R. 4135

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish a program for the collection of information relating to the use of children and individuals with mental disabilities as subjects in biomedical and behavioral research.

IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 1998

Mr. TOWNS (for himself, Mr. SHAYS, Mr. BARRETT of Wisconsin, Mr. BURTON of Indiana, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish a program for the collection of information relating to the use of children and individuals with mental disabilities as subjects in biomedical and behavioral research.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. AMENDMENT TO ESTABLISH A PROGRAM FOR**
2 **THE COLLECTION OF INFORMATION RELAT-**
3 **ING TO THE USE OF CHILDREN AND INDIVID-**
4 **UALS WITH MENTAL DISABILITIES AS SUB-**
5 **JECTS IN BIOMEDICAL AND BEHAVIORAL RE-**
6 **SEARCH.**

7 Section 491(a) of the Public Health Service Act (42
8 U.S.C. 289(a)) is amended—

9 (1) by inserting “(1)” after “(a)”; and

10 (2) by inserting at the end the following:

11 “(2) The Secretary shall establish a program for the
12 collection of information relating to the use of children and
13 individuals with mental disabilities (including mental re-
14 tardation and mental illnesses) in biomedical or behavioral
15 research subject to paragraph (1), or subject to chapter
16 V of the Food, Drug, and Cosmetic Act, or otherwise sub-
17 ject to regulation by any Federal department or agency.
18 The program may, pursuant to such paragraph, such
19 chapter, or other applicable law, include the establishment
20 of requirements for the submission of reports by Institu-
21 tional Review Boards. Information collected under the pro-
22 gram shall include information relating to—

23 “(A) description of the research subjects;

24 “(B) the nature of the research;

25 “(C) the objective of the research;

1 “(D) the reasons for the use of such subjects;

2 and

3 “(E) the source of funding for the research.

4 The Secretary shall ensure that information collected

5 under the program is made available to the public on a

6 regular basis including in the form of an annual report.”.

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